



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,300	03/06/2002	Rolf Wachter	3403-111	8886
6449 7590 09/03/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER FISHER, ABIGAIL L				
ART UNIT 1616		PAPER NUMBER		
NOTIFICATION DATE 09/03/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/030,300

Applicant(s)

WACHTER ET AL.

Examiner

ABIGAIL FISHER

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on July 11 2005 is acknowledged. Claims 1-10 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

The disclosure is objected to because of the following informalities: on page 4 of the specification mannitol is incorrectly spelt as mannit (line 27) and polyethylene is incorrectly spelt as polyetylene (line 33); on page 11, glycoside is incorrectly spelt as glykoside (line 14).

The use of the trademarks, Finsolve (page 6, line 32), Dehymulus, Lameform, Isolan, Tego Care, Cera Bellina, Chimexane, Cremophor, Admul (page 8), Carbolpol (page 10), Polymer JR, Luviquat, Lamequat, Cartaretine, Merquat, Jaguar, Mirapol (page 10), Hydageen (page 12), Uvasorb (page 15), Eusolex (page 16), Hydagen and Higcareen (page 19) have been noted in this application. **They should be capitalized wherever it appears and be accompanied by the generic terminology.**

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Additionally, the examiner is concerned with the use of the trademark Higcareen. The examiner is unsure if this trademark is miss-spelt as the examiner can find no information regarding this particular commercial available source.

Appropriate correction is required.

Claim Objections

Claim 2 is objected to because of the following informalities: diisocyanates is incorrectly spelt in the last line of the claim as diiocyanates. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as currently written is vague and indefinite. The claim recites the language "which can be obtained by". This phrase renders the claim indefinite because it is not a positive recitation of the process of which the product is made. "Can be

obtained by" implies that the preparation can be made this way but it does not necessarily have to be made this way. This results in multiple interpretations of the claim, thereby rendering the claim indefinite.

The term "substantially" in claim 4 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, it is unclear if substantially free from β -(1,6) linkages indicates that greater than 50% of the linkages are free of β -(1,6) linkages, greater than 90% of the linkages are free of β -(1,6) linkages, or some other percentage.

Claims 5 and 6 as currently written are vague and indefinite. The claims are directed to linear or branched naphthenic hydrocarbons. Applicants have not defined naphthenic. The dictionary definition (www.thefreedictionary.com/naphthenic, obtained on 8/26/08) of naphthene is cycloalkane hydrocarbons having the general formula C_nH_{2n} . Vu (US Patent No. 3597489) indicates that naphthenic hydrocarbons are cyclohexane and methylcyclohexane (claims 6 and 7). Therefore, it is unclear how a cyclic compound is linear. Furthermore, a specific example of diisocyanates utilized and claimed is hexamethylene diisocyanate. This compound is neither naphthenic nor aromatic based on the art recognized definition of naphthenic. Therefore, the instant specification provides no clear support of how a naphthenic compound is linear rendering the resulting claims indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (US Patent No. 4895724, cited in the Office action mailed on 4/15/05) in view of Vanderhoff et al. (US Patent No. 6214331).

Applicant Claims

Applicants claim a collagen free cosmetic preparation which can be obtained by cross-linking of solutions of chitosans and β -(1,3) glucans with diisocyanates and/or dialdehydes.

Applicants claim a method of preparing collagen free cosmetic preparations comprising admixing a solution which an aqueous solution of β -(1,3) adding a cross-linking agent selected from the group consisting of diisocyanates and dialdehydes and removing water from the mixture.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Cardinal et al. teach a porous matrix comprising chitosan and a dispersed molecule (abstract). The compositions of the invention are useful when injected or implanted. Examples of macromolecular pharmacological compounds include polysaccharides such as heparin and dextrin (column 2, line 21). A chitosan molecular weight of 100K-2M is specified (column 2 lines 56-59). Dissolution of chitosan and the macromolecule are disclosed (column 3 lines 12-14, 41-44). It is taught that protein stabilizer such as sugars can be incorporated (column 3, lines 65-68). Drying at low temperature under a vacuum is disclosed (column 4 lines 14-16). The chitosan may be crosslinked either before or after loading of the matrix with the macromolecule (column 4, lines 59-62). Crosslinking agents taught include glutaraldehyde as well oxidized polysaccharides such as dextran dialdehyde and starch dialdehyde (column 5, lines 3-18).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Cardinal et al. do not specify that the polysaccharide utilized is a β -(1,3) glucans such as curdlan. However, this deficiency is cured by Vanderhoff et al.

Vanderhoff et al. is directed to the process for the preparation of aqueous dispersion of particles of water-soluble polymers. The particles of the invention are use for implantation (abstract). Examples of water soluble polymers include polysaccharides (column 8, lines 22-23). Example of natural polysaccharides include natural polysaccharides such as curdlan (β -(1,3) glucan), dextran, and heparin (column 8, lines 32-37). Functional groups of the water soluble polymers include aldehydes (column 8, line 19). It is taught that these polymers can be crosslinked with crosslinking reagents such as glutaraldehyde (column 8, lines 58).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al. and Vanderhoff et al. and utilize curdlan as the polysaccharide in the invention of Cardinal et al. One of ordinary skill in the art would have been motivated to utilize curdlan as the macromolecule in the invention of Cardinal et al. as Cardinal et al. teach that polysaccharides such as dextran and heparin can be utilized as the macromolecule and Vanderhoff et al. teach that curdlan, dextran and heparin are all examples of natural polysaccharides. Alternatively, one of ordinary skill in the art would have been motivated utilize curdlan dialdehyde as Cardinal et al. teach that one type of crosslinking agent is dextran dialdehyde and Vanderhoff et al. teach that the polysaccharides can comprise functional groups such as aldehydes. One of

ordinary skill in the art would have been motivated to replace dextran with curdlan as both are taught by Vanderhoff et al. as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Moriguchi et al. (US Patent No. 4879340, cited in the Office action mailed on 4/15/05).

Applicant Claims

Applicant claims that the diisocyanates and dialdehydes are represented by the following formulas: $O=CN-[X]-NC=O$ and $OHC-[Y]-CHO$ wherein X and Y represent a linear or branched naphthenic or aromatic hydrocarbon residue with 1 to 12 carbon atoms.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach compositions comprising dextran and chitosan which are crosslinked with agents such as glutaraldehyde. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Cardinal et al. do not teach crosslinking agents of the claimed formulas. However, this deficiency is cured by Moriguchi et al.

Moriguchi et al. is directed to porous beads of chitosan. It is taught that crosslinked chitosan has superior chemical characteristics such as acid resistance and mechanical strength. Crosslinking agent utilized for crosslinking chitosan include dialdehydes and diisocyanates comprising a cyclohexylene, phenylene, methylphenylene or dimethylphenylene group (column 4, lines 9-34).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al., Vanderhoff et al., and Moriguchi et al. and utilize the crosslinking agents of Moriguchi et al. One of ordinary skill in the art would have been motivated to utilize these crosslinking agents as Moriguchi et al. teach they are crosslinking agents of chitosan that results in chitosan having superior chemical characteristics and mechanical strength.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Martin et al. (US Patent No. 6162537).

Applicant Claims

Applicant claims that natural and/or synthetic fibers are added to the mixture.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach compositions comprising dextran and chitosan which are crosslinked. The compositions are utilized for injection or implantation. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Cardinal et al. do not specify that natural and/or synthetic fibers are added. However, this deficiency is cured by Martin et al.

Martin et al. is directed to implantable fibers. It is taught that synthetic materials are known to be useful in the manufacture of many implantable articles. The more useful ones are fibers formed from synthetic polymers (column 1, lines 27-28). These fibers are often highly desirable for many implantable applications because of their mechanical properties. Furthermore, the fibers ability to be engineered into useful structures and the resulting product being able to retain these mechanical properties under conditions of the human body can be desirable (column 1, lines 33-35).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al. and Martin et al. and utilize synthetic polymer fibers in the invention of Cardinal et al. One of ordinary skill in the art would have been motivated to add these fibers because Cardinal et al. is directed to implantable material and Martin et al. teach that synthetic polymer fibers are desirable for implantable applications because of their mechanical properties.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Liu et al. (US Patent No. 6096344).

Applicant Claims

Applicant claims that the water is removed from the mixture by freeze-drying.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach porous compositions comprising dextran and chitosan which are crosslinked. Drying at low temperature under a vacuum is disclosed. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Cardinal et al. do not specify that the drying is conducted by freeze-drying. However, this deficiency is cured by Liu et al.

Liu et al. is directed to bioerodible porous compositions which comprise a porous network (abstract). It is taught that controlled dehydration via lyophilization, which is the same as freeze-drying, is preferred to avoid collapsing the porous network (column 5, lines 18-27).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al., Vanderhoff et al., and Liu et al. and utilize freeze-drying as the method for drying the composition. One of ordinary skill in the art would have been motivated to utilize freeze-drying because Cardinal et al. teach that drying at low temperature under a vacuum and Liu et al. teach that lyophilization allows for drying without collapsing the porous composition.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) the claimed invention comprises a matrix of chitosans and beta-glucans and the beta-glucans are locked into the chitosan structure and unable to escape which is contrary to the teachings of Cardinal et al.

Applicants' arguments filed July 11 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., beta-glucans are locked into the chitosan structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Cardinal et al. teach that the chitosan may be crosslinked either before or after loading of the matrix with the macromolecule. Therefore, when the macromolecule is added before crosslinking, the steps of the preparation would be the same as instantly claimed. Alternatively the crosslinking agent can be a polysaccharide dialdehyde. When the crosslinking agent utilized is this type of compound the polysaccharide, the beta-glucan, would necessarily be locked into the chitosan structure.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Johann R. Richter/

Art Unit: 1616

Supervisory Patent Examiner, Art Unit 1616